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EXAMINER	
FREDMAN, JEFFREY NORMAN	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 02/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,387	XU ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *97-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *97-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Petition

1. Applicant's petition filed January 18, 2005 was denied. Therefore, this application was not suspended and prosecution will proceed.

Priority

2. The current application is not given benefit of priority to parent applications 09/036,746 and 08/661,627 because neither of these applications provides descriptive support for the current claims. Specifically, claim 97 requires that SEQ ID NO: 1, CTCGGTACCTACTGG, be excluded. However, SEQ ID NO: 1 is not even present in either of the two cited parent applications. As MPEP 2163 notes "to be entitled to an earlier priority date or filing date under 35 U.S.C. 119, 120, or 365(c), each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure." Since the sequence limitation is not supported by the disclosure of parent applications 09/036,746 and 08/661,627, this application is currently given a priority of December 4, 1998, the filing date of 09/205,995.

Claim Rejections - 35 USC § 112, second paragraph

3. Claims 97-100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amendment to claim 97, to place the 3' and 5' positions for the sequence, creates a direct conflict with the sequence as shown in SEQ ID NO: 1, since no change was made to the sequence listing. That is, the Sequence rules, specifically 37 CFR

1.822(c)(5), note "A nucleotide sequence shall be presented, only by a single strand, in the 5 to 3 direction, from left to right." Therefore, SEQ ID NO: 1 is not the same as the sequence shown in claim 97 since the orientation of the two sequences is different. So the claim is indefinite since it is not clear which sequence is being excluded, SEQ ID NO: 1, which is 5' CTCGGTACCTACTGG 3' or the sequence which is 3' CTCGGTACCTACTGG 5' (which would be written 5' GGTCATCCATGGCTC 3' in the standard nomenclature of sequences).

Claim Rejections - 35 USC § 112, New Matter

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 97-100 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As MPEP 2163.06 notes " If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen , 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

The amendment to claim 97, to change the orientation of the sequence, is new matter. What applicant is attempting to change in this case is the orientation of the nucleic acid from 5' to 3' to 3' to 5'. There is no basis in the specification for the

statement that the sequence, as filed, was not in the 5' to 3' orientation. While Applicant argues that the 5' to 3' orientation is not universal, it is unquestionably correct that the convention and the standard and ordinary way of showing sequences in the art of biotechnology is in the 5' to 3' direction. This is evidenced from a number of sources. First, the USPTO sequence rules themselves, specifically 37 CFR 1.822(c)(5), note "A nucleotide sequence shall be presented, only by a single strand, in the 5 to 3 direction, from left to right." Second, the National Institutes of Health website has on online copy of Stryer's biochemistry at http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=stryer.section.623, which states "By convention, *the base sequence is written in the 5'-to-3'direction*. Thus, the symbol ACG indicates that the unlinked 5'-OH group is on deoxyadenylate, whereas the unlinked 3'-OH group is on deoxyguanylate. Because of this polarity, ACG and GCA correspond to different compounds (emphasis in original)." Third, the molecular biology dictionary at http://www.ppsk.usm.my/lecturers/mravi/diction.htm#DNA, states "By convention, nucleic acid sequences are written with th **5' end** at the left." Fourth, in accord with the other definitions, Freifelder in his textbook "Molecular Biology" (1983) states "Because the strands are antiparallel, a convention is needed for stating the sequence of bases in a single chain. The convention is to write a sequence with the 5'-P terminus at the left; for example ATC denotes the trinucleotide P-5'-ATC-3'-OH (see page 105)."

Therefore, the change to the sequence represents new matter because the ordinary practitioner would not have recognized that the sequence did not follow convention and was written in the antisense direction.

Claim Interpretation

6. Prior to analysis of claim 97 over the prior art, the claim must be interpreted in light of the prior art. The indefinite amendment to claim 97 specifically excludes the antisense oligomer sequence 3' CTCGGTACCTACTGG 5' (SEQ ID NO: 1). As noted in the 112, second paragraph rejection, the Sequence rules, specifically 37 CFR 1.822(c)(5), note "A nucleotide sequence shall be presented, only by a single strand, in the 5 to 3 direction, from left to right." Therefore, SEQ ID NO: 1 is not the same oligonucleotide as that shown immediately proceeding the parentheses nor is SEQ ID NO: 1 the same as that used in the Bertolino et al (International Immunol. (1991) 3(5):435-443) reference at figure 2, which is 5' GGTCATCCATGGCTC 3', but rather is the reverse sequence from that disclosed by Bertolino. The amended sequence is intended to be the same as that of Bertolino. Given the ambiguity due to the indefinite claim, two rejections will be made under the prior art. The 102 rejection will address the generic claims 97-100 where it is SEQ ID NO: 1 that is excluded. The 103 rejection will address the situation where the sequence is the Bertolino sequence which is excluded.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 97-100 are rejected under 35 U.S.C. 102(b) as being anticipated by Bertolino et al (International Immunol. (1991) 3(5):435-443).

Bertolino teaches a method for displaying an autodeterminant peptide (see abstract), in association with a MHC class II protein, on the surface of a MHC class II-positive antigen presenting cell (see abstract and page 436, column 2), comprising;

a) providing the MHC class II-positive antigen presenting cell which does not contain an exogenous construct encoding mammalian B7 molecule (see page 436, column 2, where mouse fibroblastic cells were transfected with several different vecotrs, none of which are identified by Bertolino as B7); and

b) introducing into the MHC class II-positive antigen presenting cell, a specific regulator of Ii protein expression or immunoregulatory function, the oligonucleotide CTCGGTACCTACTGG (SEQ ID NO: 1) being specifically excluded, the specific regulator consisting essentially of a copolymer of from 10 to 50 nucleotide bases, the copolymer being characterized by the ability to hybridize specifically to a target region of the RNA molecule encoding mammalian Ii protein under physiological conditions, wherein the specific regulator is characterized by the ability to inhibit Ii expression (see page 436, column 2, subheading "Antisense oligodeoxynucleotide experiments", and page 437, figure 2, where Bertolino teaches the use 5' GGTCATCCATGGCTC 3' for antisense inhibition, which is different than SEQ ID NO: 1 that is excluded, is between 10 and 50 nucleotide bases and is shownto inhibit Ii proteins in figure 3 under physiological conditions).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 97-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertolino et al (International Immunol. (1991) 3(5):435-443) in view of Koch et al (EMBO J. (1987) 6: 1677-1583) and further in view of either of Bennett et al (U.S. Patent 5,514,788), Anderson et al (U.S. Patent 5,442,049) and Cowsert et al (U.S. Patent 5,945,290)

Bertolino teaches a method for displaying an autodeterminant peptide (see abstract), in association with a MHC class II protein, on the surface of a MHC class II-positive antigen presenting cell (see abstract and page 436, column 2), comprising;

a) providing the MHC class II-positive antigen presenting cell which does not contain an exogenous construct encoding mammalian B7 molecule (see page 436, column 2, where mouse fibroblastic cells were transfected with several different vecotrs, none of which are identified by Bertolino as B7); and

b) introducing into the MHC class II-positive antigen presenting cell, a specific regulator of Ii protein expression or immunoregulatory function, the oligonucleotide CTCGGTACCTACTGG (SEQ ID NO: 1) being specifically excluded, the specific regulator consisting essentially of a copolymer of from 10 to 50 nucleotide bases, the copolymer being characterized by the ability to hybridize specifically to a target region of the RNA molecule encoding mammalian Ii protein under physiological conditions, wherein the specific regulator is characterized by the abilïty to inhibit Ii expression (see page 436, column 2, subheading "Antisense oligodeoxynucleotide experiments", and page 437, figure 2, where Bertolino teaches the use 5' GGTCATCCATGGCTC 3' for antisense inhibition, which is different than SEQ ID NO: 1 that is excluded, is between 10 and 50 nucleotide bases and is shownto inhibit Ii proteins in figure 3 under physiological conditions).

Bertolino does not teach the complete nucleic acid sequence which encodes the Ii protein, though Bertolino cites Koch for that sequence (see 442, column 2) and provides an exon/intron map in figure 2.

Koch teaches the specific sequence which encodes the Ii protein, including a sequence with 100% homology to SEQ ID NO: 40 (see attached alignment).

With regard to the specific exclusion of SEQ ID NO: 1 as well as the use of other oligonucleotides such as SEQ ID NO: 40 that are selected from the nucleic acid sequence encoding the Ii protein, each of Bennett, Anderson and Cowsert teach that selection of antisense oligonucleotides is routine in the prior art and that targets of antisense oligonucleotides include the translation initiation site (see Bennett, column 5, line 59 to column 6, line 20; See Anderson, column 5, lines 24-39; See Cowsert, column 5, lines 1-30). Cowsert further notes and teaches how to select antisense targets (see column 3) and directs antisense formation to the translation initiation site (see column 3, lines 22-35, noting "a preferred intragenic site is the region encompassing the translation initiation or termination codon of the open reading frame of the gene.").

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to select alternate sequences for inhibition of the Ii expression as taught by Bertolino from the sequence of Koch (cited by Bertolino for the sequence) since Bennett teaches,

> "Antisense oligonucleotides hold great promise as therapeutic agents for the treatment of many human diseases. Oligonucleotides specifically bind to the complementary sequence of either pre-mRNA or mature mRNA, as defined by Watson-Crick base pairing, inhibiting the flow of genetic information from DNA to protein. The properties of antisense oligonucleotides which make them specific for their target sequence also make them extraordinarily versatile. Because antisense oligonucleotides are long chains of four monomeric units they may be readily synthesized for any target RNA sequence. Numerous recent studies have documented the utility of antisense oligonucleotides as biochemical tools for studying target proteins. Rothenberg et al., J. Natl. Cancer Inst. 1989, 81, 1539-1544; Zon, G. Pharmaceutical Res. 1988, 5, 539-549). Because of recent advances in synthesis

> of nuclease resistant oligonucleotides, which exhibit enhanced cell uptake, it is now possible to consider the use of antisense oligonucleotides as a novel form of therapeutics. (3) Antisense oligonucleotides offer an ideal solution to the problems encountered in prior art approaches. They can be designed to selectively inhibit a given isoenzyme, they inhibit the production of the enzyme, and they avoid non-specific mechanisms such as free radical scavenging or binding to multiple receptors. A complete understanding of enzyme mechanisms or receptor-ligand interactions is not needed to design specific inhibitors. (see column 5, line 59 to column 6, line 20)."

So Bennett provides significant motivation to the ordinary artisan to design antisense oligonucleotides as a biochemical tool to study target proteins such as the Ii protein of Bertolino, especially where Bertolino specifically teaches the use of an antisense oligonucleotide to study the Ii protein.

Further motivation to direct the ordinary artisan to design antisense oligonucleotides specifically to the translation initiation site is provided by Cowsert, who notes "a preferred intragenic site is the region encompassing the translation initiation or termination codon of the open reading frame of the gene. (column 3, lines 22-35)". So Cowsert provides motivation to limit the preferred target selection site to a very small region of translation initiation area of the gene, limiting the number of possible targets in the Ii sequence to an extremely small genus size.

All three of Anderson, Cowsert and Bennett teach the presence of a reasonable expectation of success, with Anderson showing a table of 22 different antisense oligonucleotides at Table 4, all of which had significantly greater antisense activity than the negative control. Of course, the only oligonucleotide tested by Bertolino functioned.

With regard to the selection of the specific oligonucleotide of SEQ ID NO: 40, in the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the Court of Appeals for the Federal Circuit determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologs, however, the Court stated,

> "Normally, a *prima facie* case of obviousness is based upon structural similiarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (see page 9, paragraph 4 of attached ref)."

Since the claimed antisense oligonucleotides simply represent structural homologs of the antisense oligonucleotide of Bertolino, which are derived from sequences taught by Koch and suggested by the prior art of Bertolino as useful for antisense oligonucleotides, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed antisense oligonucleotide of SEQ ID NO: 40 is *prima facie* obvious over the cited references in the absence of secondary considerations. This is particularly the case given the suggestion of the specific region from which SEQ ID NO: 40 was derived by both Bertolino and Cowsert, who limit the number of possible species to a relatively small genus.

Response to Declaration

12. The Declaration under 37 CFR 1.132 filed December 20, 2004 is insufficient to overcome the rejection of claims 97-100 based upon 35 U.S.C. 112, first paragraph as set forth in this Office action because the Declaration argues that the new matter

regarding the orientation of the oligonucleotide of SEQ ID NO: 1 was introduced by the amendment to the sequence listing and was not present in the application as filed. This is not correct because, as noted above in the new matter rejection, the standard convention for presentation of sequences is 5' to 3'. It is textbooks and dictionaries which demonstrate this standard convention. Therefore, the sequence as filed in the original specification is necessarily presumed to be in the 5' to 3' orientation. The Applicant's filing of the sequence listing simply confirms this fact. There is no evidence in the SPECIFICATION itself which contraverts or otherwise shows that the sequence should be in any other orientation. This post facto declaration cannot change what was filed by Applicant. Therefore, the declaration is not persuasive since the sequence, as originally depicted in the originally filed specification, is consistent with the standard convention for presentation of sequences in the 5' to 3' direction, as is the originally filed sequence listing in the current case and in all the parent cases.

Response to Arguments

13. Applicant's arguments filed December 20, 2004 have been fully considered but they are not persuasive.

Fundamentally, Applicant argues that it would have been obvious that this applicant did not use the standard convention, as discussed in textbooks as old as 1983, that nucleic acids are presented in the 5' to 3' direction. Applicant argues that the sequence should be read in the 3' to 5' direction, in spite of the absence of any evidence in the specification itself that the sequence is in the 3' to 5' direction. This argument apparently intends to argue that the error is an "obvious error".

The legal standard for obvious errors, based on the MPEP 2163.07(II), is that "An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction. In re Oda, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971)." So two elements are necessary to correct the error, (1) the determination that the skilled practitioner would recognize the existence of error and (2) the determination that the skilled practitioner would recognize the appropriate correction.

The cited case, In re Oda, states (see page 6, bottom of page to page 7) "Running through the foregoing discussion of the law is the clear and basic concept that *the invention* described in the original patent must not be changed. We note, first of all, that that is not a problem in this case. The invention before us, as defined in the claims, consists of three specific chemical compounds, there is no change proposed in the claims are in the description of the claimed compounds in the specification, there is no deviation whatever with respect to the invention."

From this discussion it is clear that when the invention (which is the claims) is at issue, it cannot be changed. In particular, the Oda court makes it clear that if the chemical compounds in the claims or specification were changed, this would be new matter. In Oda, the change was in how to make the chemical compounds and at page 7, it is clear that there were four independent bases to support an identification of the subject matter at issue.

Therefore, applying the first factor from the MPEP and In re Oda, it is clear that the skilled practitioner would have no way of recognizing the error from the specification

and claims alone. Without reference to the Bertolino paper in the prior art, there is no reason to presume that the sequence would be anything other than in the 5' to 3' orientation. It would only be by using information outside of the specification, information that is new matter, that one could determine that the sequence was shown in the reverse orientaiton. For the second factor, even if the practitioner recognized that the sequence was flawed in some way, without the exogenous information from Bertolino, the skilled practitioner would not be able to recognize the appropriate correction. Consequently, the error made in this application is not an obvious error, and the change which Applicant makes in the current claim set changes "the invention" in a way that the Court in In re Oda indicated would be a problem.

Applicant relies upon introduction of the new matter to overcome the 102 rejection. However, because no new sequence listing has yet been filed, the sequence shown contradicts the sequence shown in the sequence listing. For that reason, the 102 rejection is maintained.

With regard to the 103 rejection, Applicant asserts that Bertolino does not teach an "autodeterminant peptide". This phrase is defined by the specification as "An autodeterminant peptide is herein defined as a peptide which can be bound into the antigenic peptide binding site of MHC class II molecules, for presentation to T lymphocytes (see page 33, lines 16-20)." Therefore any peptide which can be bound into the antigenic peptide binding site of MHC class II will meet the claim limitation. At page 439, Bertolino shows that the HA and HEL proteins are bound in the antigenic peptide binding site of MHC class II molecules, thereby meeting the limitation of the

claim as interpreted in light of the specification. Consequently, when reading the claim in light of the specific definition of the specification, Bertolino teaches the element that Applicant asserts is absent and the 103 rejection therefore remains proper.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
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2/8/05

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